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FEDERAL EXPRESS

Food and Drug Administration

Room 1061

5630 Fishers Lane

Rockville, MD 20852.

Attention: Director, Dockets Management Branch (HFA-305)

Re: Notice of Proposed Rulemaking
Bioterrorism Preparedness Response Act
Docket Nos. 02N-0276, 02N-0278
Our Reference: 03-4778-27(4)I

Dear Sir/Madam:

On behalf of several importers of food products, we submit the following comments concerning the Food and Drug Administration's proposed regulations implementing sections 305 and 307 of the public Health Security and Bioterrorism Preparedness Response Act, HR 3448, P.L. 107-188 ("the Bioterrorism Act"). The proposals were published February 3, 2003 at 68 Fed. Reg. 5377 and 68 Fed. Reg. 5428. The proposals amend the FDA regulations in 21 CFR to add a new subpart H with sections 1.225 through 1.243 implementing Section 305, and a new subpart I with sections 1.276 through 1.294 implementing Section 305

BACKGROUND

Sections 305 and 307 of the Bioterrorism Act require the registration of foreign suppliers of food products, and prior notice for all imported food shipments.

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Section 305 of the Bioterrorism Act requires every facility engaged in the manufacturing, processing, packing, or holding of food for consumption within the United States to register with the Secretary. Failure to register is specifically prohibited under FDCA § 301, 21 U.S.C. § 331, thus rendering the offending party subject to prosecution. Under Section 305, food produced at an unregistered facility may be held at the port of entry until the facility is registered. The product may not be sent to the consignee's premises.

Section 307 of the Bioterrorism Act requires importers of food to provide FDA with advance notification prior to entry (not to exceed five days) of the identity of all food products (with limited exceptions) to be imported into the United States. The notification must include a description of the goods, the manufacturer and shipper of the article, the country from which the article originates, the country from which the article is shipped, and the anticipated port of entry for the article. Failure to provide advance notification will be a violation of § 301 of the Act, thereby subjecting the importer to prosecution. If such notice is not provided, the article will be held at the port of entry until such notice is submitted and the Secretary determines the notification complies with the above requirements. Furthermore, for such shipments, the Secretary must also determine whether there is any credible evidence that the article of food presents a threat of serious adverse health consequences or death.

DISCUSSION

- 1. The proposed definition of "port of entry" to mean port of first arrival is not supported by the statutory language and will cause unnecessary disruption of trade.**

a) Statutory Provisions

Section 305(c) of the Bioterrorism Act amended 21 USC §381 to provide that an article of food imported or offered for import from an unregistered facility "shall be held at the *port of entry* for the article, and may not be delivered to the importer, owner, or consignee of the article, until the foreign facility is so registered." It further states that subsection (b) [of 21 USC §381] does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held."

Section 307(a) of the Bioterrorism Act amended 21 USC §381 to provide for prior notice of food imports "for the purpose of enabling such article to be inspected at *ports of entry* into the United States . . ." The notice would require identification of the anticipated "*port of entry*." Section 307(c) further amended 21 USC §381 to provide that if the prior notice requirements are not satisfied, then "the article shall be held at the *port of entry* for the article, and may not be delivered to the importer, owner, or consignee of the article, until such notice is submitted to the Secretary . . ." Furthermore, Section 307(a) specifically states that "[n]othing in this section may be construed as a limitation on the port of entry for an article of food."

b) Proposed Regulations

Proposed sections 1.227(c)(9) and 1.277(c)(5) define "port of entry" as follows:

the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e., the port where food first arrives in the United States. This port may be different than the port where the article of food is entered for U.S. Customs Service purposes.

As a consequence of this proposed regulation, all food imports covered under an immediate transportation entry to an inland port are subject to potentially lengthy detention at the port of arrival if there are any errors in the facility registration or prior notice required under the respective sections of the Bioterrorism Act. In particular, 21 USC § 381(m)(2)(B)(ii) requires FDA to subject such shipments to even greater scrutiny, thereby likely delaying release even longer.

FDA's stated rationale for this proposal is that the Bioterrorism Act is intended to give FDA better tools to deter, prepare for, and respond to bioterrorism and other food related problems. According to FDA, allowing food imported into the United States without prior

registration or prior notice to be shipped around the country and potentially lost to government oversight is inconsistent with this stated purpose. FDA further argues that consumers are best protected if food can be examined and, if necessary, be held at the point of first arrival.

c) Potential Harm of proposed regulation

Defining port of entry to equate with port of arrival or unloading is likely to cause substantial hardship for importers. Under the current regulatory process, food shipments frequently arrive at a land border or ocean port and are then moved under a transportation entry to an inland port of entry. See 19 CFR § 18.11. Entry for consumption and FDA clearance is conducted at this inland port of entry. 19 CFR §§18.12, 141.5. (Under 21 USC §381(b), the shipment may be released by Customs to the custody of the importer, secured by the entry bond [19 CFR §113.62(d),(e)], pending FDA's decision on admission. Under the Bioterrorism Act, release under bond to the importer would not be permitted for shipments lacking a facility registration or prior notice of import.) Under this process, cargo can move efficiently and expeditiously to inland ports of entry nearer to the importer's premises and/or point of distribution of the food product. Officials of Customs and FDA at this inland port have primary supervision over the entry clearance process. If there are compliance or clearance issues with the product that require interaction between the importer and government officials (e.g., relabeling), then these issues can be resolved with local officials in close proximity to the importer. In contrast, if Customs and FDA clearance were performed at a distant port of entry, the importer would be at a significant logistical and cost disadvantage if FDA detained the shipment for relabeling or compliance issues that could be best rectified by the importer at premises in close proximity.

If FDA's proposed definition of "port of entry" were adopted, then the clearance of food imports at inland ports of entry would be effectively eliminated. Importers that arrange for shipments to be entered for transportation to an inland port would run the risk that containers of product will be held up at the docks, far away from the intended port of entry. These delays could be substantial, and result from simple clerical errors in the registration or prior notice filings. This hold would prevent carriers from timely delivering cargo under an intermodal bill of lading to the inland destination, and would likely cause substantial congestion of cargo at the nation's seaports. Rail shipments from Canada go direct to an inland port under a transportation entry. It will not be feasible to stop the shipment at the border and unload a particular container. Furthermore, imports will be subject to review by two separate groups of FDA officials; those under the jurisdiction of the District encompassing the port arrival, and those under the jurisdiction of the District encompassing the inland port of entry. This will greatly increase FDA's workload.

In addition to these concerns, a specific problem may arise with respect to food shipments in which one or more of the foreign facilities has failed to properly register with FDA. If the foreign facility fails to complete the registration, then the goods must be held at the port of arrival indefinitely. There is no provision in the statute for FDA to issue a refusal of admission that would enable the importer to export the goods, or any provision for the goods to be designated as "general order" status (pursuant to which the goods could be exported). The importer could not file a consumption entry, pursuant to which FDA would issue a refusal of admission, because a consumption entry cannot be filed until the goods are arrived at the inland port. (Here, we refer to a refusal of admission under 21 USC §381(a), following which the article may be exported. A refusal of admission under section 307 of the Bioterrorism Act, 21

USC §381(m) is distinct and only results in the product being held at the port of entry pending compliance with section 307.)

For the above reasons, the proposed definition of "port of entry" should not be adopted.

d) FDA's Proposed Definition Is Unnecessary; Existing Customs Regulations Enable FDA To Carry Out Legislative Intent

FDA attempts to justify its proposed definition on the basis that allowing food articles, imported without facility registration of prior notice, to be shipped inland and "lost to government control" would be inconsistent with the statutory objective. FDA's concern is misplaced.

The critical objective of the statute is to prevent food imports from being released from Customs' control until FDA has had an opportunity to screen the shipment and determine if it presents a risk of bioterrorism. Under existing Customs regulations, all merchandise transported in bond to an inland port of entry is subject to Customs and FDA control throughout the process, to the same degree as cargo unloaded at a pier and remaining in the custody of a carrier or a local container freight station. Significantly, food unladen at the port of arrival is rarely, if ever, under the actual physical custody of Customs. Rather, it remains in the custody of a carrier (or a container station if a permit to transfer is authorized) pending Customs' issuance of release. At all times, however, it remains in Customs' legal custody, and subject to Customs' control.

The same is true for merchandise transported in bond to an inland port of entry. For example, immediate transportation entries must be reviewed and approved by Customs officials at the port of unloading, and Customs has the discretion to supervise lading of the cargo on the inbound carrier. 19 CFR §18.2. Merchandise transported in bond to an inland port of entry that is subject to detention or supervision by any Federal agency [e.g., FDA] is required to "contain a

sufficient description of the merchandise to enable the representative of the agency concerned to determine the contents of the shipment." 19 CFR §18.11(e). Thus, Customs and FDA will have sufficient information concerning inbound cargo in order to monitor its status and location, even where FDA may find the prior notice filing deficient.

In addition, and perhaps most importantly, both Customs and FDA already have full authority to detain and inspect merchandise unladen at a port of arrival to be transported inbound to an inland port of entry. Customs and FDA are not required to allow the shipment to proceed to the inland port if they believe that an inspection prior to transportation is warranted. Section 151.4 of the Customs Regulations states:

Imported merchandise shall not be opened, examined, or inspected until it has been entered under some form of entry for consumption or warehouse, except in the following cases:

(a) *Official Government examination and sampling.* Authorized employees of the Customs Service, Food and Drug Administration . . . or other Government agency may for official purposes examine or take samples of merchandise for which entry has not been filed, including merchandise being released under a special permit for immediate delivery.

Finally, the goods remain under Customs' legal control until a consumption entry is filed and a permit for release is issued.

Considering FDA already has full authority under the Customs laws to examine food imports to be transported in bond to an inland port, there is no compelling need to require that ALL shipments be held at the port arrival for any deficiency in the facility registration or prior notice filing requirements. Instead, the most efficient use of government resources would be to allow shipments to proceed to the port of entry, and to limit detentions at the port of arrival to those few shipments that FDA believes may present such a high risk that movement of the cargo should not be permitted. Upon arrival at the port of entry, shipments lacking a facility

registration will be held by the bonded carrier, or sent to a containerized freight station or general order bonded warehouse if necessary, as already provided under the Customs regulations. There is simply no credible lack of customs control under these circumstances.

e) **FDA's Proposed Definition is Unsupported by the Statutory Language.**

The language of the Bioterrorism Act does not support FDA's proposed definition of "port of entry." The statute requires simply that food shipments "be held at the port of entry." As the statute deals with the regulation of imports, it may be presumed that Congress was well-aware of the long-standing regulatory process that allows merchandise to be transported inbound and cleared at an inland port of entry. The statute specifically prohibits release of the merchandise under bond to the importer under 21 USC §381(b), but omits any prohibition on moving the merchandise under a transportation entry (under customs custody) to the port of entry designated by the importer. Had Congress intended such a limitation, it would have created it. In fact, Section 307(a) of the statute specifically states that "[n]othing in this section may be construed as a limitation on the port of entry for an article of food." FDA's proposed definition will impose the very limitation that Congress specifically proscribed. An importer could designate Chicago as its port of entry, but FDA's decision would effectively require the port to be the location where the carrier arrives to unlade the goods, thereby precluding importers of waterborne cargo from ever designating an inland port as its port of entry.

2. **The proposed regulations are inconsistent with Customs regulations concerning non-resident importers.**

Proposed section 1.285 of the regulations limits the persons that may file prior notice to a "purchaser or importer of an article of food who resides or maintains a place of business in the

United States, or an agent who resides or maintains a place of business in the United States acting on behalf of the U.S. purchaser or importer." Under this regulation, the importer must be in the US, even if the agent will submit the filing of prior notice.

Section 141.18 of the Customs Regulations specifically authorizes non-resident corporations to enter merchandise into the United States. While the non-resident importer is required to have a resident agent (the customs broker), the non-resident company may still act as importer of record. In these types of transactions, the non-resident importer typically re-sells the product to a US customer on a delivered duty paid basis. Thus, the US customer would not be involved in the Customs and FDA clearance process, and would not have access to the import entry data.

FDA's proposed definition would prohibit a non-resident importer from ever importing food products into the United States because the non-resident would not be able to file the required prior notice, nor could its customer broker (agent). As such, proposed §1.285 should be revised to allow non-resident companies importing merchandise in accordance with 19 CFR §141.18 to file prior notice of import through its resident agent customs broker. If not revised, the proposed regulation would appear to exceed FDA's authority.

3. The Information Required In the Prior Notice Filing Should Be Substantially Reduced

As drafted, proposed section 1.128 would require the prior notice to contain nearly all the information required to file an entry with FDA in connection with an entry for consumption. FDA's commentary indicates each FDA line number will equate with one prior notice. FDA's proposal goes far beyond the level of detail required under section 307 of the Bioterrorism Act,

and would effectively duplicate the information that will be transmitted to FDA once an entry for consumption is filed.

While still enabling FDA to screen suspect shipments, many of the data elements could be eliminated. For example, US Customs ACS entry number is not required by the statute. In order to provide a customs entry number, the broker would have to pre-file its customs entry in advance of arrival, even though all of the required information and documentation might not be available. And, the entry would have to be pre-filed in order for the entry number to be reflected in ACS, which would not be possible for any quota-class merchandise. See 19 CFR §142.12. These requirements impose an unreasonable burden and are not required by the law.

The proposed regulation in §1.294 should also be amended to eliminate the requirement of providing updated hour of arrival information (which must be provided to FDA if the hour of arrival time will be more than one hour earlier or 3 hours later). This is an unreasonable burden and will be virtually impossible to implement. Under the proposal, customs brokers (the entity that will be responsible for filing and amending the prior notice on behalf of the importer) will be obligated to devote considerable time and resources to monitoring arrival information in the Automated Manifest System (AMS) and filing updates with FDA. Significantly, these updates must be filed for EVERY prior notice, even if hundreds of prior notices were filed with respect to goods imported on a single vessel. Furthermore, it will be impractical, if not impossible, to amend prior notices during non-business hours. If a vessel is scheduled to arrive at noon, and the carrier updates the arrival time to 10:00 am, the broker will be unable to amend the prior notice if the update is posted to AMS after 5 pm the previous day. Similarly, it will be impossible to amend prior notice with updated arrival information over the weekend.

Considering that FDA is likely to be interested in examining a very small percentage of all food imports for purposes of detecting bioterrorism (aside from inspections for general regulatory compliance, which are typically performed after Customs release), it makes far greater sense for FDA to obtain access to the AMS from Customs, so that FDA can review the arrival status of the few vessels that contain cargo of concern. It is simply impracticable to burden importers (and their customs brokers) with this obligation, and to impose the potential liabilities on importers attendant to non-compliance. Accordingly, proposed section 1.294 should not be adopted.

In fact, much of the information required under FDA's proposed regulation is not required by the statute, such as carrier information, consignee information, customs entry information, FDA product codes, tradenames and trademarks, etc. While the name of the manufacturer and shipper are required by the statute, the phone, fax and email of these parties is not required by the statute, and may not be readily available to the importer in many instances.

It is significant to note that reduction in the information to be submitted with a prior notice in a manner consistent with the statute will avoid significant disruptions to commerce without defeating the ability of FDA to better respond to bioterrorism. Regardless of the prior notice, all of the FDA entry information must be transmitted to FDA through OASIS before Customs issues a release. If any information in that transmission causes FDA concern over the shipment, FDA can request US Customs to withhold release, or even to rescind the release and require immediate return of the goods to Customs custody. This objective can be carried out by improving FDA's ability to interact with Customs, rather than by imposing such substantial pre-entry filing burdens on importers and their customs brokers.

4. The Proposed Regulation Concerning Amendments To Prior Notice is Too Restrictive

Under proposed section 1.289, the information submitted in a prior notice may only be amended to correct (1) product identity, or (2) anticipated time of arrival. There are additional restrictions on how these amendments can be made. Under proposed §1.290, product identity may be amended only once, and only if the initial filing notified Customs that the information was incomplete and would be updated. However, the general identity of the product may not be amended at all, even if the initial filing contained a clerical error and misstated the product description, pack sizes, etc. If other information in the prior notice changes, then the initial prior notice must be canceled and a new prior notice must be filed with FDA.

The potential repercussions of this proposal on importers and customs brokers are substantial. Corrections of errors, particularly clerical errors, must be permitted. If a customs broker or importer discovers an error in the prior notice transmission (e.g., manufacturer name), but the error is not discovered in time to cancel the initial notice and refile (by noon of the day prior to arrival), then the article of food will have been imported with an inaccurate prior notice. This event might be construed as non-compliance with section 307, thereby exposing the importer, and perhaps the broker as well, with potential liability in the form of penalties assessed by Customs under 19 USC § 1595a(b) and possible prosecution under 21 USC § 331.

The proposed regulation should therefore specifically permit the filer to bring its declaration into compliance by notifying FDA of errors in the initial filing that are discovered after the noon deadline for filing prior notice.

5. The Proposed Regulations Should be Amended To Specifically Provide For Release of Compliant Articles Mixed With Non-Compliant Articles

The commentary in FDA's proposed regulations recognizes that potential difficulties will arise in circumstances in which an article of food not imported in compliance with Sections 305 and/or 307 (food from a non-registered facility, or for which prior notice was not properly filed) is shipped in a container with non food article or articles of food that are imported in compliance with Sections 305 and 307. FDA's comment is that "when mixed consolidated freight contains articles of food that must be held at the port of entry, those articles must be dealt with before the rest of the shipment proceeds." 68 Fed. Reg. 5387, 5432. Given that each article of food requires a separate prior notice, the implication of FDA's comment is that all product shipped in a single container will be subject to hold if any portion thereof is not in compliance with sections 305 and/or 307. Because the food articles held at the port of entry may not be released for a considerable period of time (the registration of prior notice must be submitted and reviewed by FDA, and FDA must respond back to the importer with its release), the portion of the shipment not covered by Sections 305 and 307 will be held at the port of entry as well.

These circumstances could arise in many different scenarios. For example, importers often purchase products from multiple manufacturers that are consolidated by a shipper prior to export. If one of the manufacturers has a deficiency in its registration, or in its paperwork accompanying the entry (e.g., typographical error in the registration number), then that article will be subject to a hold at the port of entry, and prevent release of the balance of the shipment until that error is "dealt with." If a forwarder consolidates freight for multiple consignees and only one portion of the consolidated freight is not in compliance with Sections 305 and/or 307, then the forwarder might not be able to deliver the balance of the shipment to compliant importers.

To avoid the unnecessary disruption in the release of compliant or non-regulated product, FDA's proposed regulations should be amended to clearly permit the splitting and/or deconsolidation of shipments, and filing of separate customs entries for each such portion, in any manner permitted under the Customs regulations. Specifically, 19 CFR §141.52 authorizes different portions of merchandise imported in a single shipment and consigned to a single consignee to be cleared under separate consumption entries. This would include portions covered by separate bills of lading (including house bills), and portions consigned to different ultimate consignees in the United States. Section 141.52 also authorizes separate entries for any portions of a shipment that will be covered by different types of entry, such as a bonded warehouse entry. Thus, for example, if a portion of shipment must be detained for lack of registration or notice, an initial consumption entry could be canceled, and a warehouse entry could be filed for the detained portion, and a new consumption entry filed for the compliant portion. 19 CFR §141.52(c); §144.1(c).

Under 19 CFR §19.41, cargo may be moved directly from the importing carrier to a container freight station (a Customs secure facility) for purposes of deconsolidation prior to filing any entries. Separate entries would be filed for each portion, and any portion not in compliance with Sections 305 and/or 307 could then be held at the CFS without interrupting the release of compliant cargo to compliant importers.

6. The Bioterrorism Act Does Not Require Foreign Facilities to Designate a US Agent.

The Bioterrorism Act itself does not require foreign facilities producing food to designate US agents, nor does any other provision of the Food, Drug and Cosmetic Act (FDCA). While the proposed regulations do not specifically require a foreign facility to designate a US agent,

several provisions of proposed regulations imply otherwise. Section 1.225(c) implies that foreign facilities all have US agents (which may be designated as "agent in charge") and section 1.232(f) requires foreign facilities to list the contact information of its US agent.

Foreign facilities should not be required to designate a US agent. Under proposed §1.227(c)(12), "FDA will treat representations provided by the US agent as those of the foreign facility, and consider information provided to the US agent as the equivalent of producing the same information or documents to the foreign food facility." Consequently, a foreign facility that designates a US agent is in effect required to allow a US agent to handle all official communications with the FDA. This requirement places both foreign exporters and US importers at substantial risk if a designated US agent of the foreign facility fails to fulfill its obligations.

For these reasons, §1.225(c) should be amended to state that "a foreign facility may designate ~~its~~ *a* US agent as its agent in charge" Likewise, §1.232(f) should be amended to state, in relevant part, " . . . of its US agent, *if one has been designated.*" These revisions will make it clear that foreign facilities are not obligated to designate a US agent.

7. Importing Food From an Unregistered Facility Is Not A Violation of the Act

Section 1.241(b) of the proposed regulations states that "any person who imports or offers for import an article of food without complying with the requirements of [21 USC §381(l) as set out in this subpart, or otherwise violates any requirement under section [381(l)] , or any person who causes such an act, commits a prohibited act within the meaning of section 301(dd) of the act." A person who commits a prohibited act within the meaning of section 301(dd) is

liable for prosecution under 21 USC §333, and could also be subject to Customs penalties under 19 USC §1595a(b) for importing merchandise contrary to law.

Section 301(dd) of the act does not, however, support such a broad statement of liability. That statute simply states that failure to register is a prohibited act. It does not state that importing food from a facility that is not registered (which could be the packer, shipper, or warehouse, or all three) is a prohibited act. As such, an importer does not commit a prohibited act by importing food from an unregistered facility. This distinction is critical in light of the fact that importers have no means of independently verifying that each of the relevant foreign facilities are in fact properly registered. Under §1.243 of the proposed regulations, FDA may not disclose the identity or location of a specific registered person. As such, proposed §1.241(b) should be amended to clarify that only failure to register is a prohibited act.

CONCLUSION

We respectfully request that FDA incorporate the revisions to the regulations proposed by above. If you have any questions, please feel free to contact the undersigned.

Very truly yours,

GRUNFELD, DESIDERIO, LEBOWITZ,
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